



Model M-1

USER MANUAL

CONTENT

1. Introduction	3
2. Intended Use	3
3. Limitations of Use	3
4. Warning	3
5. Essential Performance	3
6. Device Components and Operation	4
7. Cleaning	18
8. Troubleshooting	19
9. Customer Support	19
10. Repair	20
11. Disposal	22
12. Specifications	22
13. Electrical Safety and EMC	23
14. Symbol ID	28

1. Introduction

Dark adaptation is the process of the eyes adjusting to low levels of illumination. During dark adaptation, the sensitivity of the eye to light is increased. The two major components of dark adaptation are dilation of the pupil and photochemical alterations of the retina.

The AdaptDx Pro[®] device includes a headset that is worn over the eyes and a controller that is held in the patient's hand during a dark adaptation test. The patient dons the headset to create a complete light seal and then is exposed to a bright flash followed by a dim adaptation stimulus. The intensity of the adaptation stimulus is gradually extinguished. The just-detectable stimulus intensity and the time at which it is detected are periodically recorded to generate a dark adaptation threshold curve. The speed of dark adaptation recovery is characterized by a proprietary parameter called the Rod Intercept,[®] (RI[®]) which is displayed as the result of the dark adaptation test.

2. Intended Use

The AdaptDx Pro is a battery-powered, head-mounted automated dark adaptometer (biophotometer) intended to measure the time for retinal adaptation after exposure to an adapting light.

3. Limitations of Use

The AdaptDx Pro is not suitable for use with patients who are unable to follow simple instructions, operate a response button, or maintain attention for the anticipated duration of the test. The AdaptDx Pro is not suitable for use with patients who are unable to perform the Test Tutorial (See Section 6).

4. Warning

The AdaptDx Pro is not intended to be used in the diagnosis or screening of any specific ocular disease.

5. Essential Performance

When the AdaptDx Pro headset is properly connected to the handheld controller with the supplied connection cable, the AdaptDx Pro has no features that would be deemed an unacceptable risk if it malfunctions. Therefore, there is no essential performance associated with the AdaptDx Pro.

6. Device Components and Operation

Familiarizing yourself with your AdaptDx Pro is the first step in ensuring a smooth operation. Here's a road map:

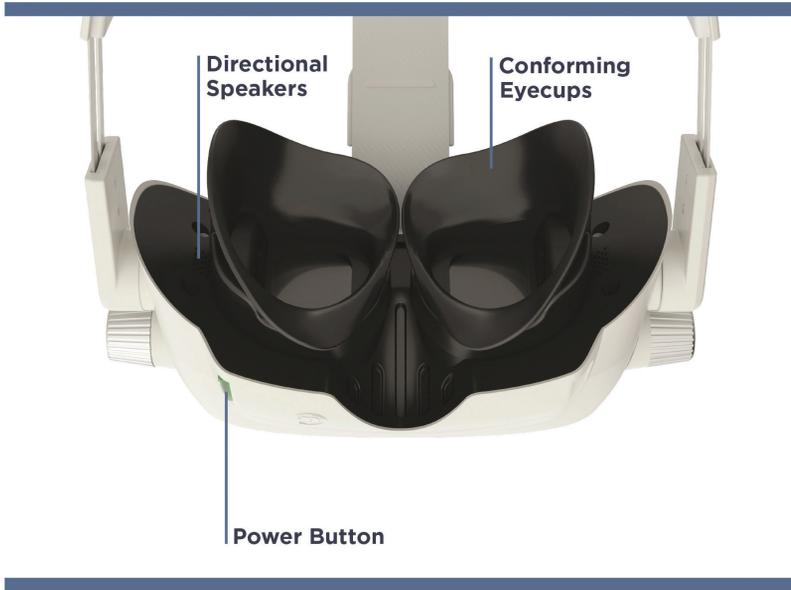


Adjustable Head Strap
with Padded Liner

Adjustable Dial

Adjustable Overhead Strap

Controller Cable



Device Components and Accessories

- **AdaptDx Pro Dark Adaptometer Headset**

- Power Button
- Focus Adjustment Knob
- Adjustable Overhead Strap
- Conforming Eyecups
- Directional Speakers

- **Handheld Controller with Rechargeable Battery (2)**

- **Wall Charger**

- **Controller Cable**

Accessories and Reorder Part Numbers

- **Adjustable Head Strap with Padded Liner – Reorder # 10384**
- **Padded Liner for Head Strap – Reorder # 10385**
- **Conforming Eyecups – Reorder # 10386**
- **Handheld Controller with Rechargeable Battery – Reorder # 10387**
- **Controller Cable – Reorder # 10388**
- **Wall Charger – Reorder # 10389**

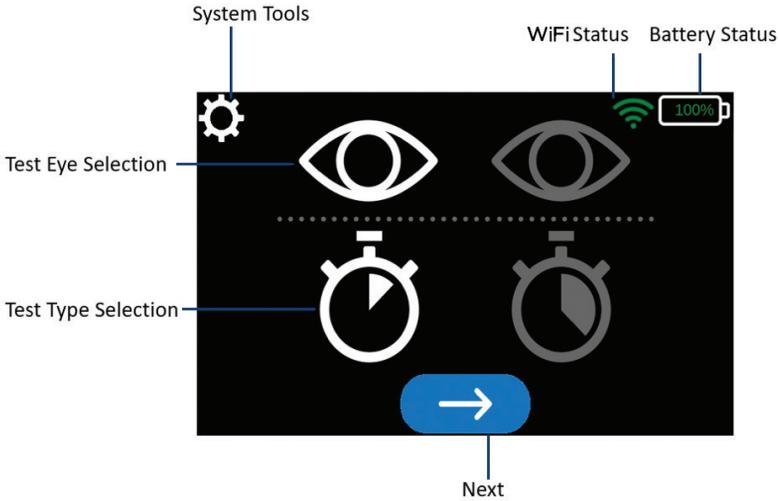
Operation

Your device comes inside this neatly packed box. Your accessories are located in a special blue drawer on the bottom of the box. Look for the silver tab and pull to retrieve the accessories.



Make sure your device is fully charged prior to operation. Connect the handheld controller to the USB-C wall charger and plug the charger into an electrical outlet. A solid green light will illuminate on the handheld controller when the device is fully charged. Disconnect the handheld controller from the charger. Plug the straight end of the USB-C cable into the handheld controller and the angled end of the cable into the device. Lastly, you can start the device by holding down the AdaptDx Pro power button until the green light turns on.

Get to Know Your Home Screen



First-time Use

You can enter your default settings when you turn on your AdaptDx Pro for the first time. The device will automatically default to the options selected the next time you turn on your device.

Via your handheld controller, select the "System Tools" icon  on at the top of your screen. Use the arrows on the left and right to scroll to the item you want to set or edit defaults.

Select language

Select the "System Tools" icon at the top of your screen. Scroll through setup options and choose "Select Language."



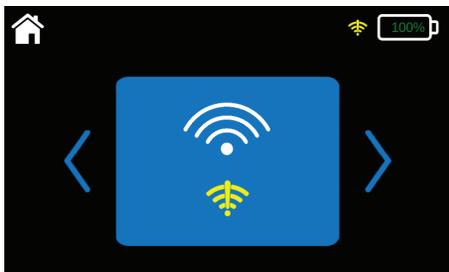
Use the arrows on the top or bottom of each item on the next screen to scroll through options (up and down arrows) for the user interface language  and patient testing audio . Once you have made your selections, navigate to the “System Tool” icon at the top of the screen to save your settings.



Set up your wireless connection

Setting up your WiFi will provide access to software updates to ensure optimal performance of the AdaptDx Pro.

Select the “System Tools” icon at the top of your screen. Scroll through setup options and choose “Select Network.”



- If connectivity parameters have been completed, the connection will be shown on the screen.

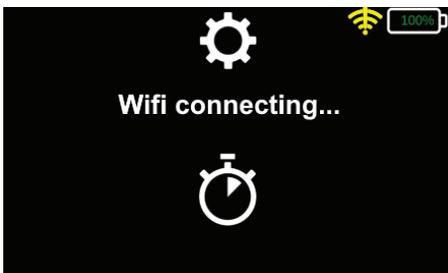
The WiFi indicator in the top right corner will be yellow  when the device is not connected.



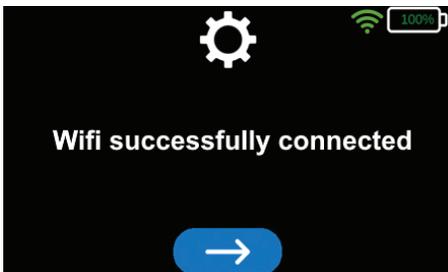
- Scroll through the available networks using the up and down arrows and choose the desired network.
- Next, enter the network password by using the up and down arrows to select each character.



- Navigate to the “Enter” button  to save the password.



- The screen will momentarily indicate that the device is establishing a connection.



- The WiFi indicator in the top right corner will turn green  when the device is connected.

- If no wireless connection has been established or to add a new connection

Set date and time

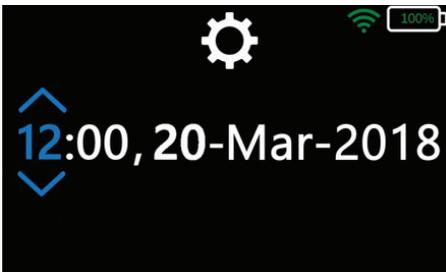
Select the "System Tools" icon at the top of your screen. Scroll through setup options and choose "Set Date/Time."



- You can choose a time zone by scrolling through the options, using the up and down arrows. Navigate to and choose the desired time zone.



- You can set the time by manually entering the time and date, by using the up and down arrows.



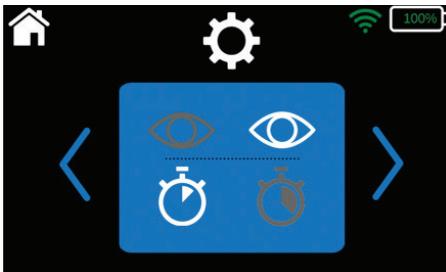
Select default eye and test

Click on the “System Tools” icon at the top of your screen. Scroll through setup options and choose the “Edit Test Defaults” screen.



- Select the default test eye. The icon on the left side of the screen indicates the right eye and the icon on the right side of the screen indicates the left eye.
- Set test type. The icon on the left side of the screen indicates the Rapid Test and the icon on the right side of the screen indicates the Extended Test.
- The Rapid Test  is a pass/fail protocol used to assess the patient's dark adaptation function and takes 2.5 to 6.5 minutes to complete. The Extended Test  provides a detailed characterization of the patient's dark adaptation function and a benchmark for monitoring changes over time. The Extended Test can take up to 20 minutes to complete, based on the severity of impairment.

For example, in this case

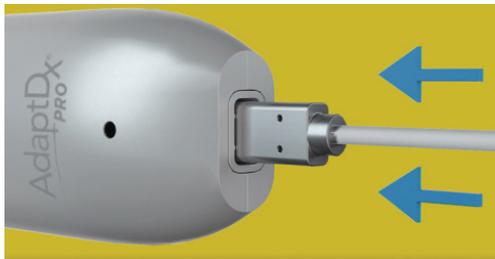


- The default settings would be Left Eye, Rapid Test. You can change your default settings at any time by selecting the “System Tools” on the home screen and repeating the process described above.

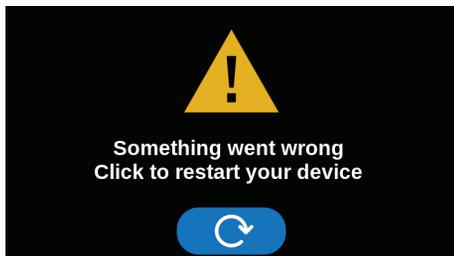
You can edit any of your default settings at any time. Simply select the “System Tools” icon at the top of your screen and choose the item to be edited.

AdaptDx Pro in Action

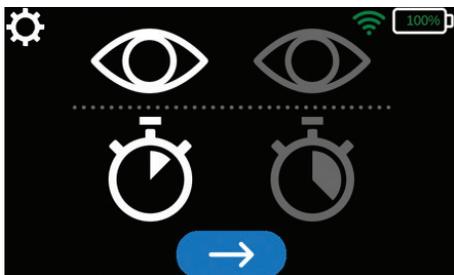
The AdaptDx Pro will run through a sequence of self-checks when you first turn it on. Your screen will display an error warning if corrective action is needed (e.g., connect the handheld controller to the headset).



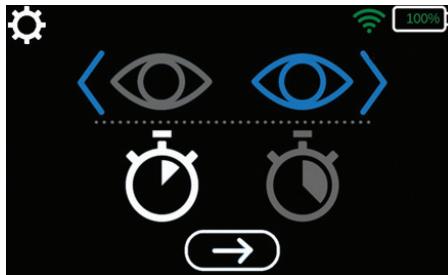
If an error is detected during self-check, you will be prompted to contact MacuLogix customer support and supplied with reference data for your case.



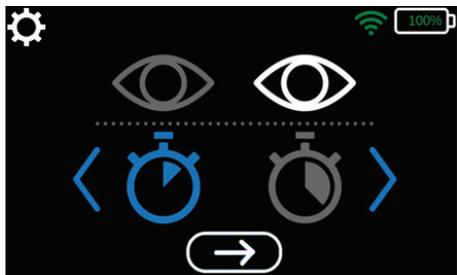
Once the self-check has been completed, the AdaptDx Pro Home screen will be displayed, showing your selected default settings. If you wish to proceed with these settings, select the blue button with the white arrow at the bottom of the screen.



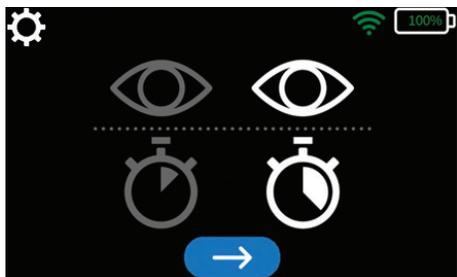
If you would like to use settings other than your defaults, select the “System Tools” icon at the top of your screen and navigate to the item you would like to change. Use the left and right arrows to make your selections. For example, if you wish to change the eye tested, navigate to the eye icon and use the arrows on the left and right to scroll through your options.



Follow the same process to change test type if needed. Click on the “timer” icon and use left and right arrows to scroll through the options.



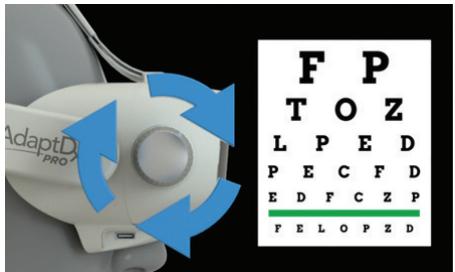
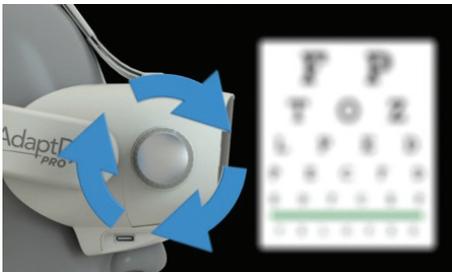
Once you have selected the test eye and the test type, select the blue button with the white arrow at the bottom of the screen.



Patient Preparation

How do we start the test?

Once test selection has been completed, an animation will provide step-by-step instructions for how to fit the headset on the patient and how the focus adjustment works.



Introduction

Theia™, the on-board technician, will introduce herself to the patient and will outline the basics of the test. At the end of the introduction, the user will be given a brief tutorial in which the pupil fixation will be established and the pupil size will be measured.

Once the test starts, a progress bar will appear on the user interface to keep the technician abreast of each step in the process.



Bleach Demonstration

Theia will ask the patient to look directly at the small red light in the center of their visual field and will instruct the patient to press the response button to verify when they see the a bright flash of light.

Stimulus Demonstration

Theia will ask the patient to look directly at the small red light in the center of their visual field and instruct the patient to press the button every time they see a spot of light in their peripheral vision. Once a threshold has been detected, photobleaching will be initiated to begin measuring dark adaptation.

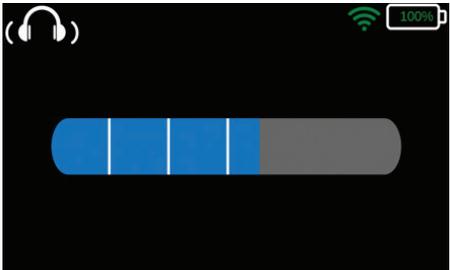
Test Administration

Theia will inform the patient that the test is about to begin. The system will automatically find and measure the patient's pupil, flash a bright light, and start the full test.

The threshold detection algorithm will initiate, and the display screen will indicate the test is underway.



Theia will automatically guide the patient through timed rest breaks. The progress bar will update after each subsequent rest break occurs.



Upon test completion, the system will pause and display the "Test Complete" screen.

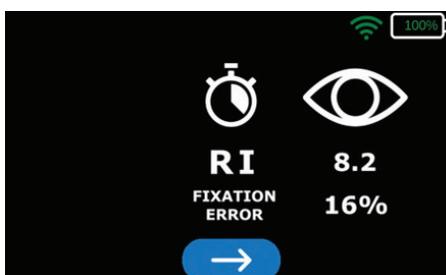
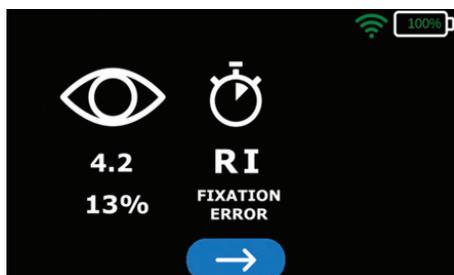


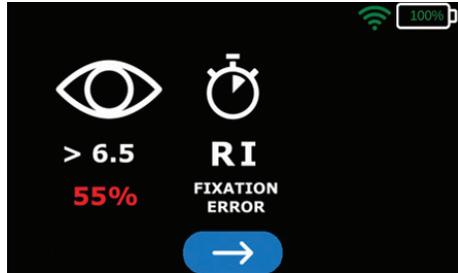
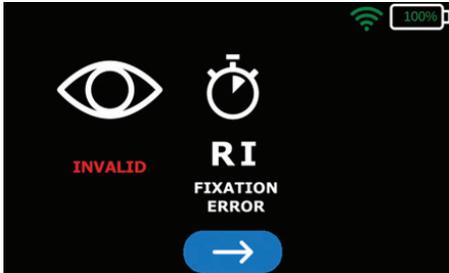
If powered down while on this screen, the unit will allow recovery of results upon reboot.

Loosen the adjustable headstrap using the dial and remove the headset from the patient's head. Using the handheld controller, the technician must now select the blue button with the white arrow on the bottom of the screen to acknowledge test completion and move to the next step.

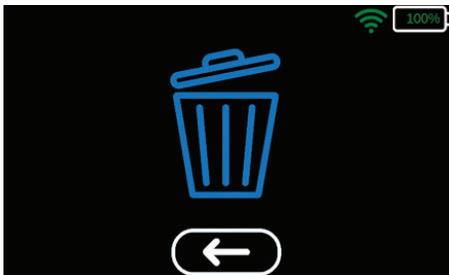
Results Review

- The Rod Intercept (RI) is the time in minutes at which the visual sensitivity recovery is complete.
- The Fixation Error is the percentage of times the patient generates invalid thresholds correlating to a loss of focus on the fixation light and an inappropriate response to the fixation light.
- An invalid test will be generated if a patient blinks or averts their gaze during photobleaching, resulting in dark adaptation that is faster than typically seen in properly bleached patients.





A warning will be generated if a bleaching error (INVALID) was detected or if the fixation error is above 30%. A bleaching error or fixation rate higher than 30% indicate the results are not valid and the patient should be retested. After photobleaching, the test eye should not be retested for at least 30 minutes to ensure a reliable test result.



The system will pause here until the technician has recorded the test results. If the system is powered down while on this screen, it will automatically display the results the next time the system is restarted. To proceed to the confirmation screen, select the blue button with the white arrow at the bottom of the screen. To return to the results screen, select the blue button with the white arrow under the “delete” icon . To confirm the results have been successfully recorded, navigate to and select the “delete” icon. The results must be deleted before proceeding to another test.

7. Cleaning

Never immerse the AdaptDx Pro in water or other fluids. Do not spray, pour or spill liquid onto the AdaptDx Pro, its accessories, connections, or openings in the device. Dry any liquid on the surface of the device immediately.

Required cleaning includes regular swabbing of the patient contact points and removal of debris from view windows, plus periodic cleaning of the display screen. The patient contact points (conforming eyecups, padded liner, adjustable headstrap, handheld controller) should be wiped between each patient. The use of isopropyl wipes is recommended. View windows should be gently cleaned with a lens cloth and/or compressed air.

8. Troubleshooting

DESCRIPTION	ACTIONS AND/OR SOLUTIONS
Unrecoverable Error (UE) Screen	The user should call customer support using the number on the screen and report the UE Code and Serial Number of the device to the technical support representative for guidance. The device will automatically power down after 1 minute. To restart the device, press and hold the power button until the power button illuminates with a green light. The device will return to the home screen.
Frozen Screen	Power down the device by holding down the power button until the green light on the power button turns off. To restart the device, press and hold the power button until the power button illuminates with a green light.
Abort Test	Press and hold the power button for 2 seconds. The device will abort the test and return to the home screen.
Handheld Controller Indicator Lights	When attaching a controller to the headset, make sure the cord is firmly seating into the USB receptacles, then press the center button to activate the indicator light. Solid Green = Full Power Flashing Green = Low Power Flashing Amber = Very Low Power The other controller should be left on the wall charger until swapped for the depleted one on the headset.

9. Customer Support

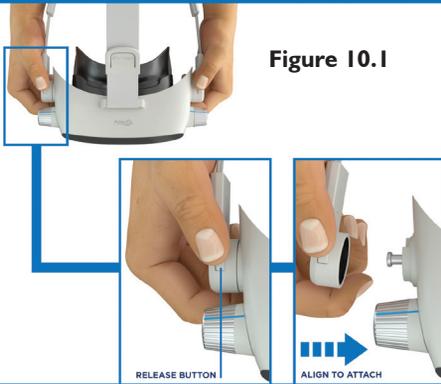
For technical support or to order supplies and replacement parts, contact MacuLogix at 1-888-392-6801, Monday through Friday between 9:00 AM and 5:00 PM US Eastern time.

10. Repair

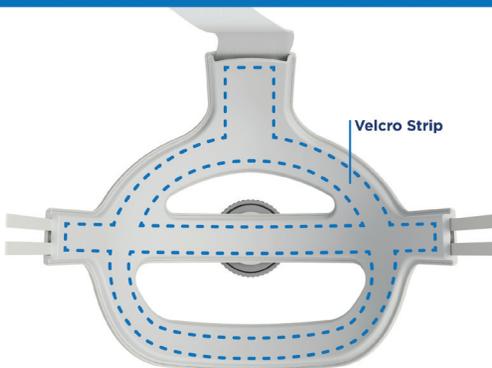
MacuLogix provides return-to-factory service for the AdaptDx Pro. Contact MacuLogix at 1-888-392-6801, Monday through Friday between 9:00 AM and 5:00 PM US Eastern time if you encounter any problems requiring maintenance.

The following components of the device can be replaced by the user.

Adjustable Head Strap – To replace the headstrap, disconnect the headstrap from the device by depressing the buttons demonstrated in figure 10.1. To connect the new headstrap, align the connections and press them into place as demonstrated in figure 10.2.



Padded Liner – To replace the padded liner, remove the padded liner from the velcro strips which are fastened to the head strap. Align the new foam liner to the head strap and firmly press over the velcro strips to ensure the foam liner is securely attached to the head strap. The proper alignment is demonstrated in figure 10.3.



Eyecups – To replace the eyecups, remove each eyecup from the device by grasping and pulling the outside corner of the conforming eyecup as demonstrated in figure 10.4. To connect the new eyecups, align the eyecup tabs to the device notches with the longer portion of the contour closest to the headstrap and press them into place as demonstrated in figure 10.5.

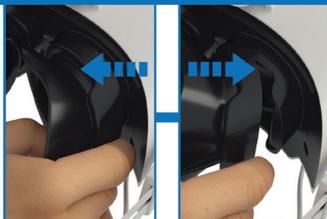


Figure 10.4



Figure 10.5

USB-C Cable – To disconnect the USB cable from the device or the handheld controller, firmly grasp the cable by the connector and disconnect it from the device. To connect the USB cable from the device or the handheld controller, firmly grasp the cable by the connector and insert the cable connector into the device connection port as demonstrated in figure 10.6 and 10.7.

Only MacuLogix supplied USB-C cables should be connected to the AdaptDx Pro device and its components.



Figure 10.6



Figure 10.7

11. Disposal

The AdaptDx Pro includes electronics, display screens, batteries and other components that may release toxic materials into the environment with improper disposal. Disposal of the AdaptDx Pro should be in accordance with applicable state and local laws for the disposal of electronic equipment.

12. Specifications

Photobleaching Subsystem

- Mechanism: flash
- Bleaching Wavelength: 505 nm
- Bleaching Intensity: 76% effective bleach

Stimulus Subsystem

- Stimulus Wavelength: 505 nm
- Stimulus Duration: 200 msec
- Stimulus Size: 2° diameter
- Stimulus Location: 5° inferior to the fixation light
- Maximum Stimulus Intensity: 20.9 scot mlx
- Dynamic Range of Stimulus: 4 log units

Fixation Subsystem

- Fixation Wavelength: 635 nm
- Fixation Intensity: 0.9 phot mlx

Operation

- Maximum Test Duration: Rapid Test is 6.5 minutes; Extended Test is 20 minutes

General

- Dimensions: 16.5 cm (height) x 22.3 cm (width) x 34.8cm (depth)
- Weight: 1.1 kg (AdaptDx Pro, AdaptDx Pro Controller and cable)
- AC Charger Specifications: 100-240VAC, 50-60Hz, 0.6A

Environmental Requirements

- Operating Limits
 - Temperature: 17° C to 27° C
 - Humidity: 20% RH to 80% RH (non-condensing)
 - Atmospheric Pressure: 700 hPa to 1,060hPa
- Transport and Storage Limits
 - Temperature: -20° C to 65° C
 - Humidity: 20% RH to 80% RH (non-condensing)
 - Atmospheric Pressure: 500 hPa to 1,060 hPa

13. Electrical Safety and EMC

AdaptDx Pro IEC 60601-I Classifications

- AC Charger – Class II (type of protection against electrical shock)
- AdaptDx Pro – Class III (type of protection against electrical shock)
- Type B (degree of protection against electrical shock)
- Ordinary IP30 (degree of protection against solid particle and ingress of water)
- Not sterile
- Not suitable for use in the presence of a flammable anesthetics mixture with air or with oxygen or with nitrous oxide
- Continuous mode of operation

Electrical Safety

The AdaptDx Pro and all its accessories are suitable for use in a patient environment. The AdaptDx Pro eyecups, foam liner, headstrap, and controller are applied parts that contact the patient.

WARNING: No modification of this equipment is allowed.

WARNING: Do not attempt to remove any of the AdaptDx Pro covers or modify the system in any way. Only an authorized AdaptDx Pro service technician should perform repairs or make modifications to the system. Removing covers or modifying the system could result in electrical shock or other safety hazards.

WARNING: Do not place any container holding liquid near the AdaptDx Pro.

Cables / Connectivity Guidelines

The following cable and connectivity guidelines must be followed to ensure compliance with the electromagnetic compatibility. Do not attempt to connect cables, USB hubs or devices to the AdaptDx Pro other than those listed.

Cable / Connectivity Guidance		
Item	Maximum Length	Comments
AdaptDx Pro Controller Battery Charger with integrated cable	4 ft / 1.2 m	Use only cable supplied by MacuLogix
Patient response button with integrated cable	4.4 ft / 1.4 m	Use only cable supplied by MacuLogix

Electromagnetic Compatibility (EMC)

The AdaptDx Pro needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided herein.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the AdaptDx Pro, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. Please see section below regarding recommended separation distances.

WARNING: The use of accessories, transducers, or cables with the AdaptDx Pro other than those specified may result in increased emissions or decreased immunity of the AdaptDx Pro.

WARNING: The AdaptDx Pro should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.

NOTE: The AdaptDx Pro contains a certified WiFi module (FCCID: TFB-1004 / IC: 5969A-1004) and RFID module (FCCID: QV5MERCURY6EN / IC: 5407A-MERCURY6EN). These modules were not tested as part of the IEC 60601-1-2 evaluation.

Guidance and manufacturer’s declaration – electromagnetic emissions

The AdaptDx Pro is intended for use in the electromagnetic environment specified below. The customer or the user of the AdaptDx Pro should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF Emissions CISPR 11	Group 1	The AdaptDx Pro uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The AdaptDx Pro is suitable for use in a typical commercial or hospital environment connected to the public low-voltage power supply network.
Harmonic Emissions IEC 61000-3-2	Class B	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity

The AdaptDx Pro is intended for use in the electromagnetic environment specified below. The customer or the user of the AdaptDx Pro should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 70% UT (30% dip in UT) for 0.5 sec. <5% UT (>95% dip in UT) for 5 sec.	<5% UT (>95% dip in UT) for 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 70% UT (30% dip in UT) for 0.5 sec. <5% UT (>95% dip in UT) for 5 sec.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the AdaptDx Pro charger requires continued operation during power mains interruptions, it is recommended that the AdaptDx Pro be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: UT is the a.c. mains voltage prior to application of the test level.

Recommended separation distances between portable and mobile RF communication equipment and the AdaptDx Pro

The AdaptDx Pro is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the AdaptDx Pro can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AdaptDx Pro as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $dd=1.17\sqrt{PP}$	150 kHz to 80 MHz $dd=1.17\sqrt{PP}$	150 kHz to 80 MHz $dd=2.33\sqrt{PP}$
0,01	0.12	0.12	0.23
0,1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note: 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note: 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection of structures, objects and people.

14. Symbol ID

1. Manufacturer



2. Model Number



3. Serial Number



4. IFU



5. EC Authorized Rep



6. Medical Device



7. CE Mark



8. Date of Manufacture



9. Electrical Markings

- DC Power



- Applied Part



10. Waste Electrical and Electronic Equipment



11. ETL Listing



12. Fragile



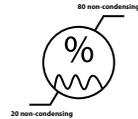
13. Keep Dry



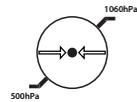
14. Temp Limit



15. Humidity Limit



16. Atmos Pressure Limit



17. Lithium Battery Warning Label



18. Do Not Re-Use

